

### **REMARKS**

In claim 12, “about” has been deleted. Also, “nitric oxide donor” has been amended to “L-arginine” to provide proper antecedent basis.

Claim 16 has been cancelled without prejudice or disclaimer.

Claim 19 has been cancelled and re-introduced as claim 30.

No new matter has been added. Claims 2-4, 7-10, 12, 14, 15, 20-23, and 27-30 are now pending for examination.

### **Claim Objections**

The Patent Office has objected to claim 19 for “improper dependency.” The Patent Office has curiously assumed that claim 19 depends from claim 16 in spite of the recitation that claim 19 depends from claim 20. However, solely to avoid any further confusion on the part of the Patent Office, Applicant has renumbered claim 19 as claim 30.

### **Rejections under 35 U.S.C. § 112, ¶ 2 and ¶ 4**

The Patent Office has rejected claims 12 and 16 under 35 U.S.C. § 112, ¶ 2, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claim 16 has also been rejected under 35 U.S.C. § 112, ¶ 4, for failing to include all of the limitations of the claim upon which it depends and for failing to further limit the subject matter of the claim upon which it depends.

Claim 16 has been cancelled without prejudice or disclaimer. Thus, it is respectfully requested that the rejection of this claim under 35 U.S.C. § 112, ¶ 2 and ¶ 4 be withdrawn.

Claim 12 has been amended to recite “L-arginine” instead of “nitric oxide donor,” thereby correcting antecedent basis. In addition, “about” has been deleted from this claim. Thus, it is respectfully requested that the rejection of this claim be withdrawn.

However, it is not conceded that “about” is indefinite. In particular, M.P.E.P. § 2173.05(b) states that terms of “relative terminology” are allowed (“The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph”), and the Patent Office has not alleged or provided any evidence that

a person of ordinary skill in the art would be incapable of understanding what was meant by “about 3 hours.”

Rejections under 35 U.S.C. § 103(a) in view of Fossel and Falk

Claims 3, 4, 7-10, 12, 14, 15, 19-23, and 27-29 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Fossel, U.S. Pat. Apl. Pub. No. 2003/0028169 (“Fossel”) in view of Falk, *et al.*, U.S. Pat. No. 5,824,658 (“Falk”).

It appears that the Patent Office has taken the position that neither Fossel nor Falk teaches or suggests rubbing a delivery vehicle into a breast. Since independent claims 4, 20, and 29 all explicitly recite rubbing a delivery vehicle into a breast, it is not seen how the Patent Office can maintain this rejection. If Falk does not teach or suggest rubbing a delivery vehicle comprising L-arginine into a breast, and Fossel does not teach or suggest rubbing a delivery vehicle comprising L-arginine into a breast, then Falk alone, Fossel alone, or Falk combined with Fossel can in no way produce this missing limitation. Thus, this rejection is improper, and should be withdrawn.

With respect to Fossel, the Patent Office states in the current Office Action that “Fossel does not expressly disclose the method comprising rubbing the delivery vehicle into the breast.” See page 6, last sentence of the third paragraph of section 22; see also page 9, second paragraph. The Patent Office states that Fossel teaches applying a nitric oxide donor to a selected area of skin, but nowhere identifies a teaching of applying a nitric oxide donor to a breast. To the contrary, the Patent Office states that Fossel does not teach or suggest that a delivery vehicle can be applied to a breast.

With respect to Falk, the Patent Office states in the current Office Action that “Falk teaches the method of treating the skin by rubbing a gel or cream by rubbing into the skin (col. 12, lines 12-15)” (page 6, fourth paragraph of section 22), and that “The reference of Falk has been brought here not for bodily incorporation of Falk’s method of treatment the particular disease [sic] into the method of Fossel, but as a teaching that it is known to apply the medication into the skin by s [sic] rubbing, and therefore, the combination is deemed to be proper,” (page 3, section 8, second paragraph). Accordingly, the Patent Office states here that Falk was supplied not for the purpose of showing that a delivery vehicle could be rubbed into a breast, but only to show that it is known to

apply a medication into the skin by rubbing. Thus, the Patent Office has not taken a position that Falk teaches or suggests that a medication or a delivery vehicle can be applied to the breast.

Accordingly, since the Patent Office has apparently taken the position that neither Falk nor Fossel teaches or suggests applying medication to a breast, it is not seen how the Patent Office can maintain this rejection. The Patent Office has not given any rational explanation as to how or why one of ordinary skill in the art would be motivated to apply a delivery vehicle to the breast after reading Falk and Fossel. The Patent Office merely states that “since Applicant claims applying the medication to the skin covering the breast that is a selected area of skin, the combination is deemed to be proper” (page 2, section 6, second paragraph). However, since the skin includes many other areas in addition to the breasts, the relationship between the skin and the breasts is a genus-species relationship, not an identity relationship. The Patent Office has identified no rational or logical reason for treating the skin and the breasts as being identical in order to maintain such a rejection.

Furthermore, with respect to independent claim 29, since the Patent Office believes that neither Fossel nor Falk teaches or suggests rubbing a delivery vehicle into a breast, the Patent Office would appear to agree that neither Fossel nor Falk teaches or suggests applying a composition to a subject diagnosed as having breast ptosis by rubbing the composition into the breast. It should be noted that in claim 29, as recited, breast ptosis is a specifically recited medical condition that is to be diagnosed, e.g., by a qualified medical clinician, yet the Patent Office has not identified where either Falk or Fossel actually teaches or suggests diagnosing a subject having breast ptosis.

Additionally, it appears that the Patent Office has not followed its own examination guidelines for determining obviousness under 35 U.S.C. § 103 as set forth in M.P.E.P. § 2141. For example, it would appear that the Patent Office is attempting to combine Fossel and Falk in order to reject the claims as being obvious. This would appear to fall under M.P.E.P. § 2143(A), “combining prior art elements according to known methods to yield predictable results.” However, in order to sustain this rejection, according to the M.P.E.P., the Patent Office must show:

- (1) a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference;

(2) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element merely performs the same function as it does separately;

(3) a finding that one of ordinary skill in the art would have recognized that the results of the combination were predictable; and

(4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

With respect to (1), the Patent Office has not demonstrated that the prior art teaches each element claimed (i.e., the breast). Regarding (2), the Patent Office has identified both references as being references that teach treating the skin by rubbing a gel or cream by rubbing into the skin. However, there is no reference that the Patent Office identified that could be combined with Fossel and Falk that would also recite rubbing a delivery vehicle comprising L-arginine into a breast for a period of time sufficient to reduce sagging. With respect to (3), the Patent Office has not demonstrated that one of ordinary skill in the art would have recognized that the results of the combination were predictable. Accordingly, the Patent Office is respectfully requested to demonstrate each of these findings, in accordance with the requirements of M.P.E.P. § 2143(A), in order to demonstrate that the claims are not patentable over the prior art of record.

Accordingly, for at least the above-described reasons, it is respectfully requested that the rejection of claims 3, 4, 7-10, 12, 14, 15, 19-23, and 27-29 be withdrawn.

Rejections under 35 U.S.C. § 103(a) in view of Fossel, Falk, and Nakata

Claim 2 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Fossel in view of Falk, and further in view of Nakata, *et al.*, U.S. Pat. No. 5,332,758 (“Nakata”).

Claim 2 depends from claim 4. For at least the reasons explained above with respect to the rejection under § 103(a) in view of Fossel and Falk, the premise of the rejection of claim 4 (that the combination of Fossel and Falk teaches all of the limitations of claim 4) is believed to be incorrect. Accordingly, while Applicant does not concede that there would have been any rational reason to combine Fossel, Falk, and Nakata in the manner suggested in the Office Action, the present rejection cannot stand, regardless. Thus, withdrawal of the rejection of claim 2 is respectfully requested.

Rejections under 35 U.S.C. § 103(a) in view of Fossel, Falk, and Marty

Claim 16 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Fossel in view of Falk, and further in view of Marty, U.S. Pat. No. 4,702,913 ("Marty").

Claim 16 has been cancelled without prejudice or disclaimer. Thus, this rejection is now moot, and it is respectfully requested that the rejection be withdrawn. However, the merits of this rejection are not conceded by the Applicant.

**CONCLUSION**

Favorable action is respectfully requested. If, for any reason, the Examiner is of the opinion that a telephone conversation with the Applicant's representative would expedite prosecution, the Examiner is kindly invited to contact the undersigned at the number below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. Please charge any fee or fee deficiency occasioned by this Response that is not covered by an enclosed check to Deposit Account No. 23/2825 under Docket No. S1509.70037US01 from which the undersigned is authorized to draw.

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Respectfully submitted,

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